Civilian Health and Medical Program Records–VA," last published at 68 FR 53784 (September 12, 2003). SSNs of CHAMPVA beneficiaries will be released to CMS pursuant to the routine use number 21 as set forth in the system notice.

RECORDS MAINTAINED BY CMS

The matching program will be conducted with data maintained by CMS in the EDB, System No. 09–70–0502, published at 67 FR 3203 (January 23, 2002). Matched data will be released to HAC pursuant to the routine use number 2 as set forth in the system notice.

INCLUSIVE DATES OF THE MATCH:

The CMP shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, whichever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. E7–9789 Filed 5–21–07; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice To Award a Grant

Program Office: Administration on Children, Youth and Families (ACYF)/ Family and Youth Services Bureau (FYSB).

Recipient Name: Medical Institute for Sexual Health.

Announcement Type: Notice to Award a Grant.

CFDA Number: 93.235.

Amount of Award: $207,400.

Project Period: 5/1/2007–4/30/2008.

Summary: This is a notice to award a grant to the Medical Institute for Sexual Health, Austin, TX, in the amount of $207,400 to support the development of online medical accuracy training for abstinence education providers.

Background: The Medical Institute for Sexual Health proposes to develop an online instructor-led workshop to train abstinence education providers in methods to access medically accurate sexual health information via the internet. Participants will learn to identify credible internet resources for sexual health information, efficiently and effectively search the internet, and answer most questions on sexual health topics.

The proposal is within the scope of technical assistance activities that the Abstinence Education Division of the Family and Youth Services Bureau (FYSB) provides to grantees with regard to integrating medical and scientific information into abstinence education programming. The Congress, in appropriating funds for the program, has directed the Administration for Children and Families (ACF) to devote up to five percent of appropriated funds for technical assistance and capacity-building for abstinence education grantees. In addition, the proposed activities of this awardee are outside the scope of the ACF's previous or proposed abstinence education competitive program announcements and would not qualify for any other existing grant opportunities.

For Further Information Contact: Stanley Koutstaal, Ph.D., Acting Director, Division of Abstinence Education, 1250 Maryland Ave., SW., Washington, DC 20024, (202) 401–9205, *Nina.Degeorge@ACF.hhs.gov.*

Dated: May 16, 2007.

Harry Wilson,

Associate Commissioner, Family and Youth Services Bureau.

[FR Doc. E7–9824 Filed 5–21–07; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005E–0248]

Determination of Regulatory Review Period for Purposes of Patent Extension; FOSRENOL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FOSRENOL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product FOSRENOL (lanthanum carbonate hydrate). FOSRENOL is indicated to reduce serum phosphate in patients with end stage renal disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for FOSRENOL (U.S. Patent No. 5,968,976) from Shire International Licensing, B.V., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FOSRENOL represented the first permitted commercial marketing or use of the product. Shortly thereafter,

the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for FOSRENOL is 2,449 days. Of this time, 1,538 days occurred during the testing phase of the regulatory review period, while 911 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: February 13, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 13, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 30, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for FOSRENOL (NDA 21–468) was initially submitted on April 30, 2002.

3. *The date the application was approved*: October 26, 2004. FDA has verified the applicant's claim that NDA 21–468 was approved on October 26, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 951 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 23, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 19, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–9787 Filed 5–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: June 13, 2007, 9 a.m.–5 p.m. June 14, 2007, 8:30 a.m.–3 p.m.

Place: Four Points by Sheraton Washington DC Downtown Hotel, 1201 K Street, NW.,Washington, DC 20005,(202)–289–7600.

Status: The meeting is open to the public with attendance limited to space availability.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department of Health and Human Services' programs that focus on reducing infant mortality and improving the health status of pregnant women and infants, and factors affecting the continuum of care with respect to maternal and child health care. It includes outcomes following childbirth; strategies to coordinate the variety of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start Program and *Healthy People 2010* infant mortality objectives.

Agenda: Topics that will be discussed include the following: Cesarean section and its effect on pre-term and infant mortality, SIDS and related causes of infant death and Preconceptional care. Proposed agenda items are subject to change as priorities indicate.

Time will be provided for public comments limited to five minutes each; comments are to be submitted no later than June 1, 2007.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM,Health Resources and Services Administration (HRSA), Room 18–05, ParklawnBuilding, 5600 Fishers Lane, Rockville, MD 20857, *Telephone:* (301) 443–2170.

Individuals who are submitting public comments or who have questions regarding the meeting and location should contact David S. de la Cruz, PhD, M.P.H., HRSA, Maternal and Child Health Bureau, *telephone:* (301) 443–6332, *e-mail: David.delaCruz@hrsa.hhs.gov.*

Dated: May 15, 2007.

Caroline Lewis,

Associate Administrator for Management.

[FR Doc. E7–9784 Filed 5–21–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605–56606 as amended November 6, 1995; and as last amended at 72 FR 19540–19544, April 18, 2007.)

This notice reflects organizational changes in the Health Resources and Services Administration, Bureau of Primary Health Care (RC). Specifically, this notice updates the mission statement of the Bureau of Primary Health Care (RC) and the functional statement of the Office of the Associate Administrator (RC), and deleted the Office of Administrative Management (RCM).

Chapter RC, Bureau of Primary Health Care

Section RC, 00 Mission

Delete in its entirety and replace with the following:

The mission of the Bureau of Primary Health Care is to improve the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services.

Section RC–10, Organization

Delete in its entirety and replace with the following:

The Bureau of Primary Health Care (BPHC) is headed by an Associate Administrator, who reports directly to